## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number

10/598,777

Confirmation No.:

1177

Applicant

Anja FECHER, et al.

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Title

TETRAHYDROPYRIDOINDOLE DERIVATIVES

TC/Art Unit

1625

Examiner:

Rita J. DESAI

Docket No.

66535.000013

Customer No.

21967

## MAIL STOP Petition

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

## Supplemental Response to Petition Decision Dated July 22, 2010

Patent Owner respectfully requests reconsideration of the Petition Decision dated

December 2, 2010 ("Petition Decision"). The Petition Decision incorrectly attributed the 75 days
between the filing of the response to the Election/Restriction (September 28, 2009) and the filing
of the Supplemental Amendment (December 12, 2009) as Applicant Delay because it incorrectly
found that the Supplement Amendment was not "expressly requested" by the Examiner and that
it therefore constituted "a failure of the applicant to engage in reasonable efforts to conclude
processing or examination of an application." As discussed below, Examiner Desai did expressly
request the claim amendments reflected in the Supplemental Amendment. Therefore, the correct
patent term adjustment (PTA) for this patent of 833 days is reflected on the face of the patent and
no certificate of correction is necessary.<sup>2</sup>

Applicant's undersigned counsel notes that the Supplemental Amendment filed December 12, 2009 was expressly requested by Examiner Desai in a telephonic interview dated December 4, 2009. Specifically, Examiner Desai proposed numerous changes to the claims that,

<sup>&</sup>lt;sup>1</sup> Under 37 C.F.R. § 1.704(c)(8), a Supplemental Amendment that is "expressly requested by the examiner" is not counted toward Applicant Delay.

<sup>&</sup>lt;sup>2</sup> Patent Owner no longer contests the 2 days of Applicant Delay related to filing the response to Election/Restriction on September 28, 2009.

if made, would put the application in condition for allowance. The December 4, 2009 Interview Summary demonstrates that the Examiner made specific proposals for claim amendments:

SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:

The examiner and the attorney discussed potential rejections, the examiner explained the 112 2<sup>rd</sup> para for C0-C5 alkylcarbonyl, C0- carbonyl would be C≃O only and chemically not possible.

The provisoes because of art make the C1-C5 alkoxycarbonyl groups also obvious, recommended deletting if.
Claims 13 had the term medicament comprising without any other ingredient, the examiner suggested changing it to
pharmaceutical composition with the carrier as given in claim 14.

Delete claim 16 and amend claim 15 to read the antogonizing as given on page 69. ( delete preventing and treating)

Applicant notes that the Supplemental Amendment included a typographical error in that it indicated that the Supplemental Amendment was in response to the telephonic interview with Examiner Desai on Friday, November 4, 2009, Monday November 7, 2009, and Tuesday November 8, 2009. The interviews, in fact, occurred on December 4<sup>th</sup>, 7<sup>th</sup>, and 8<sup>th</sup> rather than November 4<sup>th</sup>, 7<sup>th</sup>, and 8<sup>th</sup>. The error in the Supplemental Amendment is apparent on its face as November 4, 2009 did not fall on a Friday, and December 4, 2009 did fall on a Friday. Further, the December dates are contemporaneous with the Interview Summary. Accordingly, the record reflects that telephonic interviews occurred on Friday, December 4, 2009, Monday, December 7, 2009 and Tuesday, December 8, 2009 and that the Supplemental Amendment carried into effect the agreements reached between the Applicant and the Examiner.

Applicant's undersigned counsel notes that during the course of these interviews it was expressly agreed that Applicant would file a supplemental amendment to adopt these changes, rather than have the Examiner adopt the changes in an Examiner's amendment. The purpose of the interview was to circumvent the need for an additional office action, and Applicant agreed to filing a Supplemental Amendment as a courtesy to Examiner Desai so that she would avoid the need to implement all of these changes in an Examiner's Amendment. Applicant filed the Supplemental Amendment in an effort to adopt the Examiner's proposals and suggestions in order to obtain expedited allowance of the pending application. The next official act from the Patent Office after filing its Supplemental Response was to issue a Notice of Allowance on December 16, 2009. Therefore, Applicant's actions in filing the Supplemental Amendment avoided the need for the Office to issue an action on the merits and actually expedited examination.

The Petition Decision finds that the Supplemental Reply was not "expressly requested" by the Examiner under 37 C.F.R. § 1.704(c)(8), which states:

(8) Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed;

Specifically, the Petition Decision concludes that the Interview Summary does not reflect an "express request" by the Examiner but merely "a suggestion and a recommendation":

Moreover, a review of the Interview Summary relied upon by Patentees to assert that the Supplemental Amendment filed December 12, 2009 was expressly requested by the Examiner reveals that the Examiner made a suggestion and a recommendation. The Interview Summary does not contain an express request by the examiner that applicant file a Supplemental Amendment.

See Petition Decision at 2. Applicant fails to see how an express written suggestion and recommendation does not reflect an express request by the Examiner that Applicant file a Supplemental Amendment. The Petition Decision entirely ignores the fact that the *only way* Applicant could have responded to the Examiner's "suggestion" and "recommendation" was to file the Supplemental Amendment. Paradoxically, the Petition Decision implies that Applicant should have insisted the Examiner issue a formal office action setting forth additional time to reply in order to "engage in reasonable efforts to conclude processing or examination of the application." If the Petition Decision stands it will stifle the ability of examiners and applicants to reach agreement on the claims after the Applicant has filed a response to a restriction requirement. The policy reflected in the Petition Decision will therefore effectively increase pendency generally rather than reduce pendency.

The Petition Decision is diametrically opposed to official USPTO policy stating that a Supplemental Amendment implementing an agreement reached during interview will be considered as expressly requested under 37 C.F.R. § 1.704(c)(8):

Comment 35: As to proposed § 1.704(c)(12) (§ 1.704(c)(8) as adopted), one comment argued that the submission of supplemental replies should not be construed as a failure to engage in reasonable efforts because sometimes the supplemental reply expedites resolution of the issues.

Response: Section 1.704(c)(8) as adopted contains an exclusion for "a supplemental reply or other paper expressly requested by the examiner." Thus, a supplemental reply or other paper expressly requested by the examiner (e.g., a supplemental amendment carrying into effect agreements reached between the applicant and the examiner) will not be considered a failure to engage in reasonable efforts to conclude processing or examination of an application, where the filing of a supplemental reply or other paper that was not expressly requested by the examiner will be considered a failure to engage in reasonable efforts to conclude processing or examination of an application.

See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 56365, 56385 (Sept. 18, 2000) (emphasis added). The Petition Decision that the Supplemental Amendment was not expressly requested by the Examiner is therefore contrary to established USPTO policy and should be reversed. Further, the Petition Decision, as applied, is contrary to law due to its conflict with 35 U.S.C. §§ 154(b)(2)(C)(i) and 154(b)(2)(C)(iii), which only allow for reduction of patent term when "applicant failed to engage in reasonable efforts to conclude prosecution of the application." As noted above, Applicant actually expedited prosecution by filing the Supplemental Amendment carrying into effect the agreement between the Examiner and Applicant.

For the foregoing reasons, the Petition Decision improperly attributed the 75 day delay between the response to the Election/Restriction and the Supplemental Amendment to Applicant. The correct Patent Term Adjustment includes 835 days of Patent Office delay minus the 2 days attributable to the September 28, 2009 filing in the response to Election/Restriction. The correct patent term adjustment of 833 days is thus correctly reflected on the face of the patent and no certificate of correction is necessary. Patent Owner respectfully requests reconsideration of the Petition Decision and acknowledgement that the '132 Patent reflects on its front page the correct patent term adjustment of 883 days.

Finally, Applicant respectfully request clarification as to whether further Petition Decision is a final agency action within the meaning of 5 U.S.C. § 704 for purpose of judicial review. The Commissioner is hereby authorized to charge payment of any fees required for favorable reconsideration, including fees required under 37 C.F.R. §§ 1.16, 1.17, and/or 1.18, that are associated with this communication or credit any overpayment to the deposit account of Hunton & Williams, Deposit Account No. 50-0206.

Respectfully submitted,
HUNTON & WILLIAMS LLP

Date: February 2, 2011 By: /Jeff B. Vockrodt/\_

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